FDA Preliminary Public Health Notification*: Guidant VENTAK PRIZM® 2 DR and CONTAK RENEWAL® Implantable Cardioverter Defibrillators

Date: July 14, 2005

This is to provide clinicians with current information and guidance concerning malfunctions occurring with Guidant's PRIZM® 2 and CONTAK RENEWAL® implantable cardioverter defibrillator (ICD) devices, which were the subjects of a Class I recall announced by FDA on July 1, 2005.

The affected devices are:

- VENTAK PRIZM® 2 DR, Model 1861, manufactured on or before April 16, 2002
- CONTAK RENEWAL®, Model H135, manufactured on or before August 26, 2004
- CONTAK RENEWAL® 2, Model H155, manufactured on or before August 26, 2004.

The malfunction that is the subject of the recall causes damage to the device's circuitry, potentially resulting in the inability to deliver the required shock during episodes of arrhythmia. This malfunction could lead to a serious, life-threatening event. Importantly, the device does not give any sign of impending failure, and there is no test that predicts whether any particular device will fail. At this time it is not possible to provide accurate estimates of the failure rate for these devices, but at least two deaths attributable to this failure mode have been reported.

Recommendations:

If this failure mode is demonstrated to have occurred, the device should be replaced. However, the FDA is not making a recommendation on whether patients who have one of these devices should have it replaced under other circumstances. We believe that this decision must be made by the patient in consultation with his or her physician, and should be based on the patient's condition, medical history, and other pertinent factors.

We recommend that you:

1. Contact each of your patients affected by the recall, and advise coming in for an evaluation if he or she has not been seen recently. Discuss with the patient the factors that will enter into the decision regarding replacement, including medical history, the risks of replacement, device battery status, and the likelihood that this patient will require the defibrillation or pacing features of the device in the future. You may wish to provide a copy of FDA's "Advice to Patients with VENTAK PRIZM® 2 DR and CONTAK RENEWAL® Implantable Cardioverter Defibrillators" http://www.fda.gov/cdrh/medicaldevicesafety/atp/071405-guidant.html to your patients.

If the device is to be left in place, advise patients to:

- continue with their regularly-scheduled follow-up appointments;
- contact you as soon as possible if they receive a shock from the device;
- go *immediately* to your office or clinic, or to an emergency room, if they hear a "beeping" noise coming from the ICD, because this may mean that the device is damaged.

2. Verify normal device function at every patient visit, using routine clinical follow-up procedures.

    - If a shock was delivered since the prior follow-up visit, check for out-of-range values in the "Last Delivered Shock" impedance as stored in the device's memory.
    - Follow the manufacturer's instructions for evaluating warning screens encountered during interrogation of the patient's device.
    - Also check for other indicators of device malfunction, including loss of the telemetry, programming, or interrogation functions, loss of tachyarrhthmia detection and therapy, and a decrease in pacing output.

3. In order to better characterize the failure rate, it is essential that you return all explanted devices to the manufacturer for analysis, regardless of the reason for explant. All returned devices, including those that are still functional at the time of explant, are analyzed by the company to better understand their performance. In the case of patients who die with an implant, we strongly encourage interrogation and, if possible, explantation and return of the ICD.

4. Because there are no signs of impending device failure, and there is no test that predicts whether any particular device will fail, FDA has concluded that there is insufficient evidence at this time to support the value of a commanded shock.

Failure Mode Information

Guidant's laboratory analysis has determined that a breach in insulation surrounding a high voltage wire within the lead connector block, in conjunction with other circumstances, can allow undesirable shunting of energy to the active titanium case during shock delivery. Diversion of energy away from heart tissue may trigger a programmer screen message upon next interrogation, warning clinicians that full energy was not delivered to the heart during the last shock delivered. If sufficient shock energy is diverted to internal circuitry, it may render the device inoperative, preventing telemetry and delivery of additional shock therapy or bradycardia pacing. Bench testing has shown that the number of shocks delivered does not affect the likelihood of device failure.

In some of the malfunctioning devices investigated by Guidant, a yellow programmer warning screen describing low shock lead impedance or a shorted shocking lead condition was observed upon programmer interrogation post-shock. In each case, clinical evaluation of the lead system did not confirm a lead issue and for this reason each device was explanted and returned to Guidant for analysis. In some of the other cases, the yellow screen did not appear, as circuitry damage prevented programmer telemetry.

In some of the cases, a problem was identified during in-clinic cardioversion for atrial fibrillation. In the remaining cases, patients were away from the clinic, but a warning screen or loss of telemetry was observed when the patient returned to the clinic immediately following shock delivery or for a scheduled office visit.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of a Guidant ICD, you should follow the reporting procedure established by your facility. Prompt reporting of adverse events can improve FDA's understanding of and ability to communicate the risks associated with devices and assist in the identification of potential future problems.

We also encourage you to report adverse events related to ICDs that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm. Consumers can also report directly to MedWatch.

If you have questions for FDA, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 301-594-0650 and we will return your call as soon as possible.

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Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

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